

WHAT IS CLAIMED IS:

1. A method for diagnosis of blood brain barrier permeability in a subject comprising:

5 detecting levels of S100 $\beta$  protein in a blood sample derived from a subject; and  
comparing the level of S100 $\beta$  protein detected in the sample to a level of S100 $\beta$  protein in a control, wherein an increase in the level of S100 $\beta$  protein detected in the sample as compared to the control sample is indicative of blood brain barrier permeability.

10 2. The method of claim 1, wherein the sample is scored based upon permeability of the blood brain barrier.

15 3. The method of claim 1, wherein the S100 $\beta$  protein is detected using an immunoassay.

4. The method of claim 3, wherein the immunoassay is an immunoprecipitation assay.

20 5. The method of claim 1, wherein the levels of S100 $\beta$  protein in blood samples over time indicates stages of diseased states.

25 6. The method of claim 1, wherein the indication of blood brain permeability is made independent of indicators of neuronal distress.

7. The method of claim 1, further including detecting levels of markers of neuronal distress, said markers being selected from the group consisting of NSE, GFAP, and elevated levels of S100 $\beta$  protein beyond increased levels of S100 $\beta$ .

30 8. A method of treating a patient in need thereof with a therapeutic agent, said method comprising:

administering an agent which causes blood brain barrier opening;  
detecting elevated levels of S100 $\beta$  protein in the patient's blood to ensure blood  
brain barrier opening; and  
administering the therapeutic agent.

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9. The method of claim 9 further comprising the step of detecting reduced  
levels of S100 $\beta$  protein in the patient's blood to confirm a closed blood brain barrier.

10. The method of claim 8, wherein the step of detecting elevated levels of  
S100 $\beta$  to ensure blood brain barrier opening is repeated over a course of treatment of a  
patient benefiting from said blood brain barrier opening.

11. The method of claim 8, wherein said therapeutic agent is selected from the  
group consisting of: chemotherapeutics, pharmaceuticals, neuropharmaceuticals,  
potential neuropharmaceuticals, and other neurologically active agents.

12. A method for delivering a compound from the bloodstream to the brain,  
the method comprising:  
introducing an agent into the bloodstream to open the blood brain barrier;  
determining the level of S100 $\beta$  in the blood; and  
introducing the compound into the bloodstream when S100 $\beta$  protein in the  
bloodstream is elevated.

13. The method according to claim 12, comprising admitting the compound  
into the patient's bloodstream in a vicinity of the brain.

14. The method according to claim 12, wherein said compound is selected  
from the group consisting of a contrast agent, a neuropharmacologic agent, a neuroactive  
peptides, a protein, an enzyme, a gene therapy agent, a neuroprotective factor, a growth  
factor, a biogenic amine, a trophic factor to any of brain and spinal transplants, an

immunoreactive proteins, a receptor binding protein, a radioactive agent, an antibody, and a cytotoxin.

15. The method of claim 12, wherein the step of determining the level of  
5 S100 $\beta$  is repeated over a course of treatment to determine efficacy of the treatment.

16. The method of claim 12, further including the step of comparing to  
specific threshold values of the concentration of a S100 $\beta$  protein to determine the  
presence of statistically significant concentrations thereof above normal levels.

10 17. A method of diagnosing cancer, said method comprising detecting a  
cancer marker if present; and determining levels of S100 $\beta$  in a patient's blood, wherein  
elevated levels of S100 $\beta$  in the patient's blood is indicative of brain cancer.

15 18. The method of claim 17, wherein presence of elevated S100 $\beta$  protein without  
detection of the cancer marker is indicative of a primary tumor.

19. The method of claim 17, wherein presence of elevated S100 $\beta$  protein and a  
cancer marker from another organ is indicative of metastatic cancer.

20 20. The method of claim 17, wherein a patient predisposed to re-occurrence of  
a primary tumor is screened for elevated S100 $\beta$  protein in the patient's blood to indicate  
re-occurrence of the primary tumor.